UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,308	06/01/2001	Kyogo Itoh	0020-4872P	3463

2292 7590 12/03/2004

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,308	ITOH ET AL.9	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-12,16,17,19,20,28 and 29* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12,17,19,20,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

Re: ITOH *et al*
Priority Date: 30 November 1999

1. The amendment filed 9/1/2004 is acknowledged and entered into the record. Accordingly, claims 1-8, 13-15,18, and 21-27 are canceled without prejudice or disclaimer.

2. Claims 9-12,16-17, 19-20, and 28-29 are pending. Claim 16 is withdrawn from further consideration as being drawn to a non-elected invention. Applicant is reminded to cancel all claims drawn to non-elected inventions, and examined on the merits.

3. Claims 9-12,17,19-20, and 28-29 are examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

5. Applicants request for rejoinder of claim 16 has been carefully considered but ise not deemed persuasive. Claim 16 is drawn to a peptide comprising specific sequences of SEQ ID No: 19-21 of which have been withdrawn due to an election of species (see paper mailed 8/4/2003). Applicant elected SEQ ID No: 5 as the species for examination on the merits, of which SEQ ID No: 5 was found to be present in the prior art. Because SEQ ID No: 5 was found in the prior art, no other sequences were searched. Thus the withdrawal of claim 16 as being drawn to a non-elected species is deemed appropriate. The restriction requirement has been made final in the paper mailed 8/4/2003.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

6. The rejection of claims 9-10,17,19-20,28, and 29 under 35 USC § 112, 1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that the instantly claimed invention meets the written description requirements. More specifically, applicant argues that although the process for determining whether a protein is a tumor associated antigen (TAA) is difficult, once such a determination is made, the art provides "methods for identifying and preparing tumor antigen peptides from the tumor antigen protein" and that such determinations and preparation are within the purview of the skilled artisan (see page 9 and 10 of response). Applicant's substantiate their arguments by providing exhibit 1 (Rammensee *et al*, Immunogenetics 1995;41:178-228), which provides guidance on methods of determining binding motifs and ligands (see page 10 of response). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The fact patterns associated with this case are analogous to those provided in example 13 of the Interim Written Description Guidelines (see http://www.uspto.gov/web/offices/pac/writtendesc.pdf). Example 13 claim 2 teaches protein variants of a specifically named protein identified by a specific sequence identification number. In that example, it was determined that because the genus of protein fragments was considered highly variant due to the number of possible structural differences between each member of the genus, the written description could not be adequately satisfied through the disclosure of a single sequence identification number. In the instant case, the specification teaches a novel protein, termed ART-1 (SEQ ID No: 1), of which has

been identified in the instant application as a TAA. Applicant have determined that certain peptide fragments ranging in lengths of 8-14 amino acids found within SEQ ID No: 1 may be associated with eliciting a T-cell response. Applicant proceeds to disclose various sequences found within ART-1 (such as SEQ ID No: 3-18) and several variants (see SEQ ID No: 19-21), from this, Applicant's claim a genus of any peptide fragment of 8-14 amino acids in length found within SEQ ID No: 1 or variants with specific modifications at position 2 of the peptide sequence (i.e. SEQ ID No: 19-21) as their invention. However, applicant has not provided sufficient written description to be entitled to the highly variant and unpredictable genus of peptides as broadly claimed. Because the claim is drawn to a genus of peptides, of which is not solely limited to those found in SEQ ID No: 1, and because the specification fails to provide common attributes or core structural attributes representative of all possible species of 8-14 amino acids peptides, the written description requirement has not been meet. Aside from the obvious relationship of the fragments (i.e. being derived from SEQ ID No: 1) the peptide sequences do not share any predictable relationship. The art recognized determination of HLA-binding motifs alone does not suffice as fulfilling the requirement because there are countless possibilities of peptides found within SEQ ID No: 1 or in other proteins that may share a common 8-14 amino acid motif. As such, the widely varying sequences which are encompassed by the claims and those disclosed in the specification do not share any structural commonality and would not allow the skilled artisan to predictably determine which sequences are encompassed by the claims. Furthermore, disclosure of SEQ ID No: 3-21, alone is not representative of the varying

peptides encompassed by the claims because there are no core structural features shared by the sequences. And lastly, the general knowledge of the art does not supplement the lack of specific disclosure in the specification, because specific, not general, guidance is what is needed.

It is noted also that the amendments to claims 11-12 and 16 to specifically recite fragments by reference to sequence identification numbers has overcome the written description rejection. Applicant's arguments concerning SEQ ID No: 3-5 is noted, however, the amendments to the claims (i.e. claims 11-12) have overcome the written description rejection for claims specifically reciting SEQ ID No: 3-5.

Therefore, the rejection of claims under 35 USC 112, 1st paragraph as lacking written description is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 9-12, and now claims 17,19,20, 28-29 under 35 USC § 102(b) is maintained for the reasons of record. Applicant arguments are substantially similar to those previously presented in a paper filed 2/4/2004. The arguments will be reiterated hereto. Briefly, applicant argues that Nagase *et al* do not teach peptides of 8-14 amino acids in length, nor do they teach the functional aspects of the peptide as claimed by the applicant and thus one of skill in the art would have not have anticipated the instant rejection. Applicant additionally points out and states "every limitation in the claim must be considered" (see page 13 of response). Applicant's arguments have

been carefully considered but are not deemed persuasive to overcome the rejection of record.

As previously stated, the claims are interpreted as a peptide comprising 8-14 amino acids in length that is a fragment of SEQ ID No: 1. The claims do not specifically limit the peptides from being more than 8-14 amino acids in length and would therefore read on the full length protein from which the 8-14 amino acids peptide sequences are derived. Nagase *et al* teach a protein that is identical to that of SEQ ID No: 1 and thus would anticipate the claims drawn to peptides as currently interpreted. The functional limitations of the claims are inherent properties of the protein, and absent evidence to the contrary the protein as claimed by Nagase *et al* would have the same function. Thus the rejection of claims 9-12 under 35 USC 102(b) as being anticipated by Nagase *et al* is maintained for the reasons of record.

Newly rejected claims 17,19-20, and 28-29 are also anticipated by Nagase *et al* because the claims as currently amended are drawn to a composition, a recombinant polypeptide, and a diagnostic agent that comprises a peptide of 8-14 amino acids in length that is a fragment of SEQ ID No: 1. As stated above, because the claims are interpreted as being "open" and comprising 8-14 amino acids of SEQ ID No: 1, the claims are anticipated by Nagase *et al* because they teach a protein that is identical to SEQ ID No: 1. Furthermore, because the process of making the peptide (unless the process conveys some structural difference to the product), and the intended use of the product is given little patentable weight, claims 19, 28, and 29 are anticipated because the claimed peptides are identical to the protein taught by Nagase *et al*. Additionally,

claim 28 is also anticipated by Nagase *et al* because they teach a DNA encoding a protein that is identical to that of SEQ ID No: 1, (see attached sequence alignment, Exhibit A)

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 9/4/204.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
November 22, 2004

Exhibit A
1 of 2

ALIGNMENTS

RESULT 1
O94864
ID   O94864   PRELIMINARY;   PRT;   414 AA.
AC   O94864;
DT   01-MAY-1999 (TrEMBLrel. 10, Created)
DT   01-MAY-1999 (TrEMBLrel. 10, Last sequence update)
DT   01-MAR-2001 (TrEMBLrel. 16, Last annotation update)
DE   KIAA0764 protein (Adenocarcinoma antigen ART1).
GN   KIAA0764.
OS   Homo sapiens (Human).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
OX   NCBI_TaxID=9606;
RN   [1]
RP   SEQUENCE FROM N.A.
RC   TISSUE=BRAIN;
RX   MEDLINE=99087487; PubMed=9872452;
RA   Nagase T., Ishikawa K., Suyama M., Kikuno R., Miyajima N., Tanaka A.,
RA   Kotani H., Nomura N., Ohara O.;
RT   "Prediction of the coding sequences of unidentified human genes. XI.
RT   The complete sequences of 100 new cDNA clones from brain which code
RT   for large proteins in vitro.";
RL   DNA Res. 5:277-286(1998).
RN   [2]
RP   SEQUENCE FROM N.A.
RX   MEDLINE=20441578; PubMed=10987294;
RA   Nishizaka S., Gomi S., Harada K., Oizumi K., Itoh K., Shichijo S.;
RT   "A new tumor-rejection antigen recognized by cytotoxic T lymphocytes
RT   infiltrating into a lung adenocarcinoma.";
RL   Cancer Res. 60:4830-4837(2000).
DR   EMBL; AB018307; BAA34484.1; -.
DR   EMBL; AF197954; AAG28523.1; -.
SQ   SEQUENCE   414 AA; 46192 MW; 59724A96353D44D5 CRC64;

  Query Match   100.0%; Score 2175; DB 4; Length 414;
  Best Local Similarity 100.0%; Pred. No. 1.8e-166;
  Matches 414; Conservative   0; Mismatches   0; Indels   0; Gaps   0;

Qy   1 MNLQRYWGEIPISSSQTNRSSFDLLPREFRLVEVHDPPLHQPSANKPKPPTMLDIPSEPC 60

[redacted]

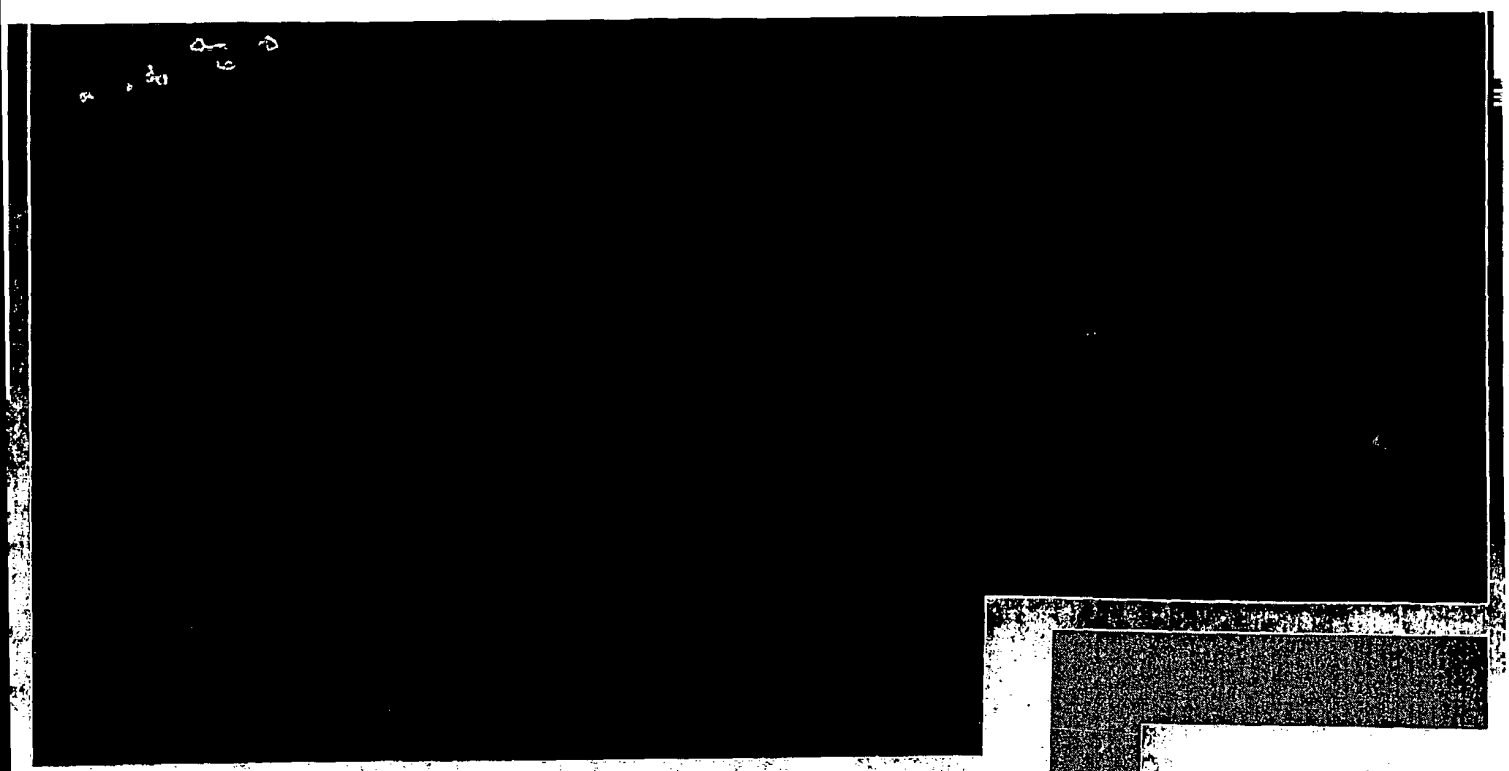

Exhibit
2 of 2

Mon Jul 21 15:58:07 2003 us-09-857-

```
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MNLQRYWGEIPISSSQTNRSSFDLLPREFRLVEVHDPPLHQPSANKPKPPTMLDIPSEPC 60

Qy         61 SLTIHTIQLIQHNRRLRNLIATAQAQNQQQTEGVKTEESEPLPSCPGSPPLPDDLLPLDC 120
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 SLTIHTIQLIQHNRRLRNLIATAQAQNQQQTEGVKTEESEPLPSCPGSPPLPDDLLPLDC 120

Qy        121 KNPNAPFQIRHSDPESDFYRGKGEPVTELSWHSCRQLLYQAVATILAHAGFDCANESVLE 180
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 KNPNAPFQIRHSDPESDFYRGKGEPVTELSWHSCRQLLYQAVATILAHAGFDCANESVLE 180

Qy        181 TLTDVAHEYCLKFTKLLRFAVDREARLGQTPFPDVMEQVFHEVGIGSVLSLQKFWQHRIK 240
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 TLTDVAHEYCLKFTKLLRFAVDREARLGQTPFPDVMEQVFHEVGIGSVLSLQKFWQHRIK 240

Qy        241 DYHSYMLQISKQLSEEYERIVNPEKATEDAKPVKIKEEPVSDITFPVSEELEADLASGDQ 300
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 DYHSYMLQISKQLSEEYERIVNPEKATEDAKPVKIKEEPVSDITFPVSEELEADLASGDQ 300

Qy        301 SLPMGVLGAQSERFPSNLEVEASPQASSAEVNASPLWNLAHVKMEPQESEEGNVSGHGVL 360
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 SLPMGVLGAQSERFPSNLEVEASPQASSAEVNASPLWNLAHVKMEPQESEEGNVSGHGVL 360

Qy        361 GSDVFEEPMSGMSEAGIPQSPDDSDSSYGSHSTDSLMGSSPVFNQRCKKRMRKI 414
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 GSDVFEEPMSGMSEAGIPQSPDDSDSSYGSHSTDSLMGSSPVFNQRCKKRMRKI 414

RESULT 2
Q9H2T6
```

Document

US006121239
Total (1)